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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
WHITEMAN, BRIAN A	

ART UNIT	PAPER NUMBER
1635	

DATE MAILED: 10/19/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/708,952	BENTWICH, ITZHAK	
	Examiner	Art Unit	
	Brian Whiteman	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-15 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-15 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-15 are pending.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-4, drawn to an isolated oligonucleotide that anneals to a portion of a mRNA transcript of a target gene, wherein said oligonucleotide has at least 80% sequence identity with a nucleotide sequence selected from SEQ ID NOs: 1-14456, classifiable in class 536, subclass 24.3.

II. Claims 5 and 6, drawn to an isolated oligonucleotide that anneals to a portion of a mRNA transcript of a target gene associated with HIV-1 infection, wherein said oligonucleotide has at least 80% sequence identity with a nucleotide sequence selected from SEQ ID NOs: 1, 3, 5, and 63804-66308, classifiable in class 536, subclass 24.3.

III. Claims 7 and 8, drawn to an isolated oligonucleotide that anneals to a portion of a mRNA transcript of a target gene associated with HIV-2 infection, wherein said oligonucleotide has at least 80% sequence identity with a nucleotide sequence selected from SEQ ID NOs: 1, 3, 5, and 63309-68740, classifiable in class 536, subclass 24.3.

IV. Claims 9 and 10, drawn to an isolated oligonucleotide that anneals to a portion of a mRNA transcript of a target gene associated with Human adenovirus A, wherein said oligonucleotide has at least 80% sequence identity with a nucleotide

sequence selected from SEQ ID NOs: 3 and 18799-20253, classifiable in class 536, subclass 24.3.

V. Claims 11 and 12, drawn to an isolated oligonucleotide that anneals to a portion of a mRNA transcript of a target gene associated with Human herpesvirus 1, wherein said oligonucleotide has at least 80% sequence identity with a nucleotide sequence selected from SEQ ID NOs: 1, 3, 4, and 29296-31435, classifiable in class 536, subclass 24.3.

VI. Claims 13 and 14, drawn to an isolated oligonucleotide that anneals to a portion of a mRNA transcript of a target gene associated with Human herpesvirus 4, wherein said oligonucleotide has at least 80% sequence identity with a nucleotide sequence selected from SEQ ID NOs: 1, 3, 4, 36686-40656, classifiable in class 536, subclass 24.3.

VII. Claim 15, drawn to a method for bioinformatics detection of microRNA oligonucleotides, classifiable in class 435, subclass 6.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because the oligonucleotide can be selected from a distinct SEQ ID NO: and the complement oligonucleotide could from a different SEQ ID NOs. The subcombination has

separate utility such as inhibiting a target gene from a target gene associated with HIV-1 infection. The search for each group is not coextensive because the search for each group would not overlap. Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions have acquired a separate status in the art due to their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Inventions I and III are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because the oligonucleotide can be selected from a distinct SEQ ID NO: and the complement oligonucleotide could from a different SEQ ID NOs. The subcombination has separate utility such as inhibiting a target gene from a target gene associated with HIV-2 infection. The search for each group is not coextensive because the search for each group would not overlap. Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions have acquired a separate status in the art due to their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Inventions I and IV are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the

subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because the oligonucleotide can be selected from a distinct SEQ ID NO: and the complement oligonucleotide could from a different SEQ ID NOs. The subcombination has separate utility such as inhibiting a target gene from a target gene associated with Human adenovirus A. The search for each group is not coextensive because the search for each group would not overlap. Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions have acquired a separate status in the art due to their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Inventions I and V are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because the oligonucleotide can be selected from a distinct SEQ ID NO: and the complement oligonucleotide could from a different SEQ ID NOs. The subcombination has separate utility such as inhibiting a target gene from a target gene associated with Human herpesvirus 1. The search for each group is not coextensive because the search for each group would not overlap. Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because

the inventions have acquired a separate status in the art due to their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Inventions I and VI are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because the oligonucleotide can be selected from a distinct SEQ ID NO: and the complement oligonucleotide could from a different SEQ ID NOs. The subcombination has separate utility such as inhibiting a target gene from a target gene associated with Human herpesvirus 4. The search for each group is not coextensive because the search for each group would not overlap. Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions have acquired a separate status in the art due to their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

The examiner has required restriction between combination and subcombination inventions. Where applicant elects a subcombination, and claims thereto are subsequently found allowable, any claim(s) depending from or otherwise requiring all the limitations of the allowable subcombination will be examined for patentability in accordance with 37 CFR 1.104. See MPEP § 821.04(a). Applicant is advised that if any claim presented in a continuation or divisional application is anticipated by, or includes all the limitations of, a claim that is allowable

in the present application, such claim may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application.

Inventions II-VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). The instant case specification does not disclose the inventions are capable of use together. Each group is directed to different structure and targeting a gene from a different virus. This would result in a different effect. Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

Inventions I-VI and Invention VII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case, each product can be used to inhibit a target gene from a distinct disease in cells in vitro as opposed to diagnosing microRNAs.

Searching the inventions of Groups I-VII together would impose a serious search burden. The inventions of Groups I-VI and VII have a separate status in the art as shown by their different classifications. Moreover, in the instant case, the search for the oligonucleotide and the method for bioinformatics detection of microRNA using an oligonucleotide are not coextensive.

The search for group VII would require a text search for the method for bioinformatics detection in addition to an oligonucleotide search. Moreover, even if the oligonucleotide product were known, the method for bioinformatics detection, which uses the product may be novel and unobvious in view of the preamble or active steps.

If applicant elects Groups I-VI, another restriction is required.

Claims 1-14 set forth in Groups I-VI contain more than 10 independent and distinct nucleotide sequences. See MPEP 2434. For the reasons set forth above the groups are distinct and independent. To avoid a lengthy office action and to help expedite prosecution of the instant application, the examiner will include claims 1-14 in the restriction even though the claims are in different groups.

Claims 1-14 are subject to a restriction since it is not considered to be a proper genus/Markush. See MPEP 803.02 - PRACTICE RE MARKUSH-TYPE CLAIMS - If the members of the Markush group are sufficiently few in number or so closely related that a search and examination of the entire claim can be made without serious burden, the examiner must examine all the members of the Markush group in the claim on the merits, even though they are directed to independent and distinct inventions. In such a case, the examiner will not follow the procedure described below and will not require restriction. Since the decisions in In re Weber, 580 F.2d 455, 198 USPQ 328 (CCPA 1978) and In re Haas, 580 F.2d 461, 198 USPQ 334 (CCPA 1978), it is improper for the Office to refuse to examine that which applicants regard as their invention, unless the subject matter in a claim lacks unity of invention. In re Harnish, 631 F.2d 716, 206 USPQ 300 (CCPA 1980); and Ex parte Hozumi, 3 USPQ2d 1059 (Bd. Pat. App.

& Int. 1984). Broadly, unity of invention exists where compounds included within a Markush group (1) share a common utility, and (2) share a substantial structural feature disclosed as being essential to that utility.

Claims 1-14 specifically claims nucleic acid (NA) molecules comprising a sense strand and an antisense strand to target RNA: SEQ ID NOS: 1-14456 for claims 1-4; SEQ ID NOS: 1, 3, 5, 63804-66308 for claims 5 and 6 and SEQ ID NOS: 196685, 197420, 198047 and 194813-200687 for claim 5; SEQ ID NOS: 1, 3, 5, 66309-68740 for claims 7 and 8 and SEQ ID NOS: 202601, 204421, 205326, and 200688-206410 for claim 7; SEQ ID NOS: 3 AND 18799-20253 for claims 9 and 10, and SEQ ID NOS: 99724 and 99658-102371 for claim 9; SEQ ID NOS: 1, 3, 4, 29296-31435 for claims 11 and 12 and SEQ ID NOS: 119609, 119788 and 119381-124109 for claim 11; SEQ ID NOS: 1, 3, 4, 36686-40656 for claims 13 and 14 and SEQ ID NOS: 134996, 135760 and 134776-142920 for claim 13, which are targeted to and modulate the expression of gene sequences. Although the NA sequences claimed each target and modulate expression of a RNA, the instant NA sequences are considered to be unrelated, since each NA sequence claimed is structurally and functionally independent and distinct for the following reasons: each NA sequence has a unique nucleotide sequence, each NA sequence targets a different and specific region of a target gene nucleic acid, and each NA, upon binding to a gene nucleic acid, functionally modulates (increases or decreases) the expression of the gene and to varying degree. As such the Markush/genus of NA sequences in claims 1-14 is not considered to constitute a proper genus, and is therefore subject to restriction. Furthermore, a search of more than one (1) of the NA sequences claimed in claims 1-14 presents an undue burden on the Patent and Trademark Office due to the complex nature of the search and corresponding examination of

more than one (1) of the claimed NA sequences. In view of the foregoing, one (1) NA sequence is considered to be a reasonable number of sequences for examination. Accordingly, applicants are required to elect one (1) NA and (1) complement for each group.

Note that this is not a species election.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double

patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Whiteman whose telephone number is (571) 272-0764. The examiner can normally be reached on Monday through Friday from 7:00 to 4:00 (Eastern Standard Time), with alternating Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras, SPE – Art Unit 1635, can be reached at (571) 272-4517.

Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center. The faxing of

such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The Fax Center number is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Brian Whiteman